IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF NORTH CAROLINA
WESTERN DIVISION

ISLET SCIENCES, INC., Plaintiff, v. AVOLYNT, INC., BRIGHTHAVEN VENTURES, LLC, WILLIAM WILKISON, and JAMES GREEN, Defendants. And AVOLYNT, INC., BRIGHTHAVEN VENTURES, LLC, WILLIAM WILKISON, and JAMES GREEN, Third-Party Plaintiffs, v. ISLET SCIENCES, INC., JOHN F. STEEL, IV., LARRY K. ELLINGSON, JAMES A. HARPER, RICHARD D. PILNIK, EUGENE M. MANNHEIMER, and GARY R. KEELING, Counterclaim/Third-Party Defendants.	:	5:19-CV-145-D

ISLET SCIENCES, INC.'s MEMORANDUM IN SUPPORT OF ITS MOTION FOR LEAVE TO FILE THIRD AMENDED COMPLAINT

INTRODUCTION

This lawsuit is about Defendants' breach of, and other wrongful conduct relating to, a joint venture agreement with Plaintiff Islet Sciences, Inc. ("Islet") to develop and commercialize medications containing Remogliflozin ("Remo"). In discovery, Islet sought information about the various ways Defendants have attempted to commercialize Remo—and, in turn, the damages Islet suffered. Defendants have stonewalled these efforts, asserting that Islet's claims are limited to Defendants' use of Remo in standalone "monotherapies" for the treatment of diabetes and do not include Remo if it is used in combination therapies developed after Defendants' breach of the joint venture agreement.

This ongoing discovery dispute reached a crescendo on December 18, 2022, when the Court denied Islet's motion for clarification and found that the scope of discovery was limited to Remo monotherapies for diabetes developed before the joint venture ended. The Court based its decision on its interpretation of the Second Amended Complaint ("SAC" or "Complaint") (ECF No. 53), including that "Remo Technology" was defined as "a new class of drug [] directed to the treatment of type 2 diabetes and related conditions" (SAC ¶1) that included "the molecule Remogliflozin ('Remo') and its salt carrier ('Remo Etabonate')" (SAC ¶27). The Court further instructed that Islet's "remedy" to include later-developed Remo drugs is "amendment" of the Complaint. ECF No. 206 at 6. Islet had believed that the Complaint had covered any use of the Remo molecule or its salt carrier for any diabetes-related treatment indication because Remo was developed during the Parties' relationship and was the direct focus of the joint venture. However, in light of the Court's Order denying Islet's request for clarification concerning the scope of discovery, Islet now follows the Court's guidance by amending its Complaint to explicitly include therapies, developed at any time, that include Remo (whether alone or in combination with other drug molecules) for any treatment indication. The proposed Third Amended Complaint, attached

here, makes only this single, simple change. **Ex. 1**, Islet's Third Amended Complaint; **Ex. 2**, Blackline: Islet's Third Amended Complaint.

There can be no claims of surprise or prejudice to Defendants: Islet has made clear for many months that it considered Remo combination therapies to be within the scope of its claims. Islet simply seeks to make explicit what it has always intended to be the scope of this lawsuit. Good cause exists to allow the proposed amendment.

BACKGROUND

In 2010, Defendant Brighthaven Ventures, LLC ("BHV") licensed the rights to develop Remo, a molecule with promising applications to treat diabetes and other metabolic diseases. Defendants had also developed a novel delivery formulation to avoid common side effects associated with Remo (the "Biphasic Formulation"). By 2012, however, after failing to find investors or a business partner, Defendants faced a series of existential problems: (1) rapidly approaching patent filing deadlines; (2) the inability to raise approximately $4,500,000 to advance Remo to the next clinical stage; (3) the lack of money to pay for non-extendable patent filings that over their lifetime could exceed $500,000; (4) owing $800,000 in development costs to the licensor of Remo; and (5) facing default on an approximate $300,000 business development loan. All of these issues were set to converge in January of 2013, when BHV faced a non-extendable patent filing deadline that it could not have met without Islet's assistance.

With time running out, Defendants enticed plaintiff Islet with their promising technology, ultimately leading to a joint venture to "collaborate to develop and commercialize" Remo under which equity ownership would be split 80% to Islet and 20% to BHV. SAC, ECF No. 53, Ex. 1 at 1. Through this deal, Islet loaned Defendants its patent lawyers, helped Defendants secure extensions for their drug development payments and loan obligation, and most importantly, preserved Defendants' relationship with the licensor of Remo.

Without Islet's assistance in the joint venture, Defendants would not have secured intellectual property rights in Remo, and never would have developed Remo. In other words, *all* profits resulting from Remo—in any form—is traceable to the joint venture and Islet's contributions.

Once the patent applications were filed and the development and commercialization of Remo had begun, Defendants breached the Joint Venture, dissolving the relationship with Islet with the intent of capturing the value of Remo—estimated at that time by Defendants to be more than several *billion in peak year sales*—for themselves.

Since the joint venture dissolved, Defendants have: (i) continued to sell Remo as a standalone monotherapy; (ii) combined Remo with other compounds to create other therapeutics; and (iii) in other instances simply rebranded Remo for treatment of different diseases.

Islet's damages from Defendants' breach of the Joint Venture and other wrongful conduct (*e.g.*, unjust enrichment) are measured by Islet's expectation damages and Defendants' ill-gotten gains. Those gains include not only the value of Remo as a standalone monotherapy, but also Remo in combination with other drugs. In short, Islet is entitled to its share of the value of the Remo intellectual property that it helped secure, whether that value is derived from the use of Remo alone or in combination with other drugs.

Defendants have insisted on a narrow construction of Islet's claims, asserting that they include only Remo's original standalone form. On this basis, Defendants have objected to multiple discovery requests seeking information regarding their use of the Remo Technology—forcing Islet to bring multiple motions to compel to obtain information about the full spectrum of Remo products that Defendants have developed. As Defendants themselves recognized, these motions

sought to compel discovery pertaining to their "exploitation of Remo in all territories, *for all applications, at any time*." ECF No. 141, First Opp. Br., at 4 (citations omitted) (emphasis added).

The Court granted Islet's first motion to compel, which sought discovery on "all applications" of Remo, in February 2021. *See* ECF No. 150. In that Motion, Islet argued that it needed to discover "how the Remo Technology was, is, or **will be,** situated in the market for treatment of metabolic diseases, like diabetes and [nonalcoholic steatohepatitis] NASH" and to learn of "possible therapies that may be derived" from Remo. ECF No. 135, Islet's First MTC at 3–4 (emphasis added). Further, Islet argued that the requested information would show "the inherent value of the Remo Technology, as measured by its potential for future commercialization." *Id.* at 8 (emphasis added). Defendants attempted to limit discovery to particular Remo indications in the Term Sheet—namely, the "[p]revention, diagnosis and treatment of human metabolic diseases of Type 1 and Type 2 diabetes mellitus." ECF No. 141, Opp. to First MTC at 6 (citations omitted). By granting the First Motion to Compel, Islet believed that the Court found Islet was entitled to discover information about all Remo and Remo-combination drugs—regardless of their indications or inclusion in later-developed therapies. ECF No. 150.

Islet later filed a second motion to compel seeking to obtain documents relating to monotherapies of a different drug, "Miza." ECF No. 167. The Court ruled that discovery on Miza monotherapies was precluded, because any damages "related to drugs or technology other than the Remo Technology"—defined as "a diabetes treatment using the molecule Remogliflozin ('Remo') and its salt carrier ('Remo Etabonate')"—was "not relevant to [Islet's] damages claim."[1] ECF No.

[1] Islet's Complaint defined Remo Technology as "directed to the treatment of type 2 diabetes and *related conditions*," (SAC ¶1) (emphasis added), and further noted that the "Remo Technology

191 at 7. "If Islet wants to pursue damages beyond this," the Court advised, "it will need to attempt to amend its complaint to do so." *Id.* at 8.

Islet understood this second Order to be consistent with the first: any applications that used Remo were within the scope of Islet's claims, while drugs and technology that did *not* use Remo in at least some manner (such as Miza monotherapies) were not. Islet was therefore surprised when Defendants continued to resist efforts to obtain discovery regarding Remo used in combination with other drugs, asserting that Islet's claims were limited Remo as a monotherapy.

On October 27, 2022, Islet moved for Clarification and/or Reconsideration of the Court's ruling on the second motion to compel, asking the Court to make clear that any application of Remo was within the scope of Islet's claims. The Court sided with Defendants: Islet was "not entitled to discovery about Remo combination drugs," and the "remedy" for this limitation was "amendment." ECF No. 206 at 6. This motion seeks to amend the Complaint in precisely that manner.

ARGUMENT

Federal Rule of Civil Procedure 15(a)(2) provides that a party "may amend its pleadings only with the opposing party's written consent or the court's leave." Fed. R. Civ. P. 15(a)(2). "The court should freely give leave [to amend the complaint] when justice so requires." *Id*.

As the Supreme Court explained in *Foman v. Davis*, this liberal standard requires compelling cause to deny parties an opportunity for full and fair resolution of their disputes:

> If the underlying facts or circumstances relied upon by a plaintiff may be a proper subject of relief, he ought to be afforded an opportunity to test his claim on the merits. In the absence of any apparent or declared reason—such as undue delay, bad faith or dilatory motive on the part of the movant, repeated failure to cure deficiencies by amendments previously allowed, undue prejudice to the opposing party by virtue of allowance of the

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also has huge economic value due to its unique potential to treat Non-Alcoholic Steatohepatitis ('NASH')" (SAC ¶31).

> amendment, futility of amendment, etc.—the leave sought should, as the rules require, be "freely given."

371 U.S. 178, 182 (1962).

The Fourth Circuit upholds this permissive standard. *See U.S. ex rel. May v. Purdue Pharma L.P.*, 737 F.3d 908, 920 (4th Cir. 2013). "This means that a request to amend should only be denied if one of three facts is present: 'the amendment would be prejudicial to the opposing party, there has been bad faith on the part of the moving party, or amendment would be futile.'" *Mayfield v. Nat'l Ass'n for Stock Car Auto Racing, Inc.*, 674 F.3d 369, 379 (4th Cir. 2012) (quoting *Matrix Cap. Mgmt. Fund, LP v. BearingPoint, Inc.*, 576 F.3d 172, 193 (4th Cir. 2009)).[2]

None of the factors that would justify refusing leave to amend are present here. Islet's proposed amendment would merely clarify the scope of its claims and allow Islet to recover the damages arising from Defendants' wrongful conduct, as it has sought from the beginning.

I. DEFENDANTS WILL NOT BE UNDULY PREJUDICED.

In the context of Rule 15(a), "prejudice means that the party opposing the amendment would be hindered in the preparation of its case, or would have been prevented from taking some measure in support of its position." *Markel Am. Ins. Co. v. XDS, LLC*, 516 F. Supp. 3d 507, 509 (E.D.N.C. 2021). For example, "undue prejudice may justify denying a motion to amend if the amendment would require the non-moving party to expend significant additional resources to conduct discovery and prepare for trial, or would significantly delay the resolution of the dispute." *Id.* Yet even if "a new legal theory is alleged" that "would entail additional discovery and evidentiary burdens on the part of the opposing party," this "basis for a finding of prejudice essentially applies where the amendment is offered shortly before or during trial." *Scott v. Fam.*

[2] The Court has also instructed that at this stage of the action a motion for leave to amend must also meet the standards of Federal Rule of Civil Procedure 16. *See* ECF No. 110 at 2. Under Rule 16(b)(4), a scheduling order may be modified for "good cause and with the judge's consent."

Dollar Stores, Inc., 733 F.3d 105, 118–19 (4th Cir. 2013) (quoting *Johnson v. Oroweat Foods Co.*, 785 F.2d 503, 510 (4th Cir. 1986)). By contrast, where parties are "still in discovery, and many steps removed from trial," claims of purported undue prejudice are "overstated." *Scott*, 733 F.3d at 119; *see also Hillyard Enters., Inc. v. Warren Oil Co.*, No. 5:02-CV-329-H, 2003 WL 25904136, at *5 (E.D.N.C. July 3, 2003) ("Since the court recently amended the scheduling order to extend the time for discovery, any prejudice that might have resulted will be adequately mitigated.").[3]

Another factor militating against a finding of prejudice is the non-moving party's familiarity with the claims as amended, and with the facts underlying the proposed amended claims. For example, the Court may find that there is no prejudice where the non-moving party has "been on notice" of the proposed amended claims. *Hall v. Int'l Union, United Auto., Aerospace & Agric. Implement Workers of Am., UAW*, No. 3:10CV418-RJC-DSC, 2011 WL 13223638, at *2 (W.D.N.C. May 31, 2011); *see also Davis v. Piper Aircraft Corp.*, 615 F.2d 606, 613 (4th Cir. 1980) ("Because defendant was from the outset made fully aware of the events giving rise to the action, an allowance of the amendment could not in any way prejudice the preparation of the defendant's case.").

It is also relevant that a proposed amendment will draw upon information in the non-moving party's possession; a court may find there is no prejudice where the facts underlying the amended claims "could be taken from [the non-movant's] own records." *See Gray v. Laws*, 915 F. Supp. 747, 757 (E.D.N.C. 1994) (citing *Frank M. McDermott, Ltd. v. Moretz*, 898 F.2d 418, 421

[3] "[T]he Fourth Circuit has a well-established rule that '[d]elay alone, without prejudice, does not support the denial of a motion for leave to amend.'" *N.C. Farm Bureau Mut. Ins. Co., Inc. v. Clear Tech., Inc.*, No. 5:12-CV-111-BO, 2013 WL 12165679, at *1 (E.D.N.C. Apr. 9, 2013) (quoting *Pittston Co. v. United States*, 199 F.3d 694, 705 (4th Cir. 1999)); *see also Ward Elecs. Serv., Inc. v. First Com. Bank*, 819 F.2d 496, 497 (4th Cir. 1987) (noting that "mere delay absent any resulting prejudice or evidence of dilatoriness" is "not sufficient justification for denial").

(4th Cir. 1990) (no prejudice where the proposed amendment "was based entirely on documents taken from [the nonmovant's] own records, and no additional discovery would have been necessary, nor would additional third-party witnesses have been required to testify on the issue")).

There can be no serious claim of undue prejudice here. The legal theories underlying Islet's claims are unchanged; the heart of the case continues to be Defendants' breach of, and wrongful conduct pertaining to, the joint venture. The only effect of the very limited amendment is to explicitly allege what Islet had repeatedly notified Defendants was at issue all along: Remo in all applications, including in combination drugs developed after the dissolution of the parties' joint venture.

Defendants have been on notice for over a year that Islet construed its claims to include all applications of Remo.[4] The Court itself twice forecast to Defendants that, if Islet's claims were to be more narrowly construed, a motion for leave to amend would likely be forthcoming. ECF No. 191, Order on Mot. to Compel at 7–8; ECF No. 206, Order on Mot. for Clarif. at 6. Defendants therefore cannot genuinely claim to be surprised after repeated motion practice and the Court's guidance on this specific amendment.

Furthermore, any facts or documents relating to Defendants' use of Remo combination therapies are not only in Defendants' possession—they are *uniquely* in Defendants' possession.

[4] Indeed, Defendants' initial attempts to resist Islet's discovery requests for information about these combination drugs—in particular, "AVO-1681" and "AVO-3500," was founded not on a contention that Remo used in combination with other drugs was not within the scope of the claims—but rather that these applications do not require Remo at all. *See* ECF No. 172 at 5. This position is contradicted by Defendants' own documents (*see* ECF No. 168-6, BHV0410564–612 at 571, 578; ECF No. 168-7, BHV0402162–203 at 164) and the testimony of its own officers (*see* ECF No. ECF No. 197-1, Cheatham Tr., at 151:18–20 (confirming that AVO-1681 is a "straight Remo drug") and 143:23–144:1 (confirming that AVO-3500 is "a unique chemical entity composed of Remogliflozin and another drug")). Only after being made to acknowledge that Remo is a component of AVO-1681 and AVO-3500, did Defendants claim that these combination uses are beyond the scope of Islet's claims.

Islet became aware of Defendants' development of the Remo combination therapies only after Defendants were ordered to produce that information by the Court's order granting Islet's first motion to compel. In fact, although Defendants claim these combination therapies (*e.g.*, "AVO-3500"—a combination of Remo and Miza) "are beyond the scope of the claims and defenses here," they nevertheless claim to have "produced any non-privileged documents of which they are aware regarding those conceptual projects that are responsive to the requests targeting them." ECF No. 172 at 6. If true, then the amendment will require little additional discovery. What follow-up tasks remain (*e.g.*, depositions) will be largely incidental to the discovery already required under the existing Complaint.

In addition, while discovery in this action has lagged—largely due to Defendants' own conduct—we are still far from trial. Discovery is to be completed by March 20, 2023. The trial itself remains a distant prospect. Simply put, there is no basis for asserting that Defendants would be prejudiced by the proposed amendment.

II. ISLET HAS ACTED IN GOOD FAITH.

The other factors to be considered in ruling on a Rule 15(a) motion to amend are much less significant than the first. Prejudice is the "touchstone of the inquiry under rule 15(a)." *In re S. E. Materials, Inc.*, No. ADV 11-6035, 2012 WL 1899221, at *2 (Bankr. M.D.N.C. May 24, 2012) (citing *Lone Star Ladies Invest. Club v. Schlotzsky's Inc.*, 238 F.3d 363, 368 (5th Cir. 2001)). Thus, the "absence of prejudice, though not alone determinative, will normally warrant granting leave to amend." *Hillyard Enters., Inc.*, 2003 WL 25904136, at *4. Because there can be no serious claim of undue prejudice, Islet's Motion should be granted on that basis alone. Nevertheless, the additional factors also support allowing leave to amend.

Islet has acted at all times in good faith. To act in "bad faith" is to act with "[d]ishonesty of belief or purpose"—meaning, "to act for the wrong reasons." *United States ex rel. Nicholson v.*

MedCom Carolinas, Inc., 42 F.4th 185, 198 (4th Cir. 2022) (quoting Black's Law Dictionary (8th ed. 2004)). "It may be outright lying, deceiving, playing unjustifiable hardball, slacking off, intentionally causing confusion, or stubbornly refusing to follow rules—you can imagine cases where a party just wants to cause chaos—or it might be something as mundane as noticing someone's mistake and saying nothing about it." *Id.*

Nothing of the sort has happened here. As of the outset of this action, the only use of Remo of which Islet was aware was the original monotherapy. *See* SAC, ECF No. 53 ¶¶ 30–31. Notably, until the Court granted Islet's first motion to compel, Defendants had produced hundreds of thousands of pages which were scrupulously scrubbed of any mention of later developed mono or combination applications of Remo. *See* Decl. of Francisco A. Villegas ("Villegas Decl.") ¶¶ 4-6.

References on Defendants' website, however, suggested ongoing development of Remo for NASH. *See* ECF No. 135-5, Ex. C ("Remogliflozin is a selective SGLT2 inhibitor and potent anu-oxidant in development for nonalcoholic fatty liver disease ('NAFLD')/nonalcoholic steatohepatitis ('NASH') and type 2 diabetes.") (May 2, 2019). The inconsistencies between the Defendants' discovery responses and their public statements about Remo's development led to a long series of letters and telephone conferences between the Parties, culminating in Islet's first motion to compel. Mere weeks after the Court's order on Islet's first motion to compel, on March 8, 2021, Defendants produced documents containing (for the first time) references to AVO-3500[5] and AVO-1681[6]—new therapeutics which, Islet later learned, were created by combining Remo

[5] As stated earlier, AVO-3500 is Defendants' code for a Remo and Miza combination drug for the treatment of NASH.

[6] AVO-1681 is Defendants' internal code for a Remo monotherapy for the treatment of Primary Sclerosing Cholangitis ("PSC") and Primary Biliary Cholangitis ("PBC")—both conditions that Islet contends are related to diabetes.

with other component drugs. *See* Villegas Decl. ¶¶ 7–8.[7]

Islet's discovery requests prior to this production did not specifically reference these allegedly later-developed combination applications because Defendants *prevented Islet from learning about them*. Nevertheless, whether Remo was used in a standalone application or in tandem with other drugs, Remo is the same drug, and so Islet believed the combination applications were every bit a part of its claims as the standalone applications. Indeed, Defendants claim that, in response to the Court's order on the first motion to compel, they have "produced any non-privileged documents of which they are aware" regarding AVO-3500 and AVO-1681. ECF No. 172 at 6. Thus, notwithstanding Defendants' assertion that these projects "are beyond the scope of the claims and defenses here" (*see id.*), it appeared to Islet that Defendants had acquiesced in light of the Court's order. Were it otherwise, Defendants could have filed a motion for clarification or reconsideration—but they did not. Thus, Islet believed for many months that the scope of the action had been settled, and that all Parties understood Islet's claims addressed any use of Remo, including combination therapies developed after the joint venture period.

Following the Court's denial of Islet's second motion to compel and its request for clarification or reconsideration, Islet is doing the very thing the Court said it should do: amend the Complaint to make the scope of its claims clear. Nothing suggests that Islet has acted dishonestly or for improper reasons. There was an honest disagreement as to the scope of Islet's claims, the Court sided with Defendants on this issue, and Islet is responding accordingly.

[7] Islet also subsequently learned that AVO-3500 is the specific therapeutic used to treat NASH—an application Islet specifically referenced in its pleadings. *See* SAC, ECF No. 53 ¶ 31. Thus, while Islet was initially unaware that this application involved a use of Remo in combination with another molecule, Islet's claims have always addressed the range of applications to which Remo could be put to use. *See also id.* ¶ 1 (discussing Remo as "directed to the treatment of type 2 diabetes *and related conditions*") (emphasis added).

Thus, Islet acts in good faith in bringing this Motion and its proposed amendment to the SAC.

III. THE PROPOSED AMENDMENT IS NOT FUTILE.

A proposed amendment is "futile if the claim it presents would not survive a motion to dismiss." *Save Our Sound OBX, Inc. v. N.C. Dep't of Transp.*, 914 F.3d 213, 228 (4th Cir. 2019) (citation omitted). A motion to amend a pleading should be denied as futile only if a proposed amendment advances a claim or defense that is frivolous or legally deficient on its face. *See Johnson v. Oroweat Foods Co.*, 785 F.2d 503, 510 (4th Cir. 1986) (rejecting futility argument where legal deficiency was "not obvious on the face of the proposed amendment") (citing *Davis*, 615 F.2d at 613 ("Unless a proposed amendment may clearly be seen to be futile because of substantive or procedural considerations, *conjecture about the merits of the litigation should not enter into the decision whether to allow amendment*." (emphasis added) (citation omitted)).

The proposed amendment not futile. The legal theories set forth in the proposed Third Amended Complaint are unchanged. Defendants have already tested their legal sufficiency through a motion to dismiss, and the Court denied their motion. *See* ECF No. 79. To the extent Defendants might challenge Islet's damages theories, such as unjust enrichment pertaining to the proposed amendment, controlling authority makes clear that Islet's theories are viable. For example, damages in quasi contract are calculated by reference to the value of the benefit to the defendant and not the market value of the services rendered by the plaintiff. *Werlin v. Reader's Digest*, 528 F. Supp. 451, 467 (S.D.N.Y. 1981); *Precision Testing Lab'ys, Ltd. v. Kenyon Corp. of Am.*, No. 84 CIV. 5424 (IBC), 1988 WL 34825, at *2 (S.D.N.Y. Apr. 6, 1988) ("case law has reiterated that damages for unjust enrichment are calculated by reference to the actual *value of the benefit to the defendant* and not the market value of the services rendered by the plaintiff.") (emphasis added). Here, Islet "is entitled to a portion of the *earnings and profits* of [Defendants]

which were generated as a result of [Islet's] efforts . . . [t]o hold otherwise would defeat the purpose of restitution: it would allow defendants to benefit at the expense of plaintiff." *Precision Testing Lab'ys, Ltd.*, 1988 WL 34825, at *2 (emphasis added).

The drugs disputed in Islet's second motion to compel, AVO-1681 and AVO-3500, are assets within Islet's damages remedies. For example, the Restatement (Third) of Restitution and Unjust Enrichment, describes *disgorgement* as a remedy for the Defendants' opportunistic breach of contract: "a claimant under this section may recover the defendant's profits from breach, even if they exceed the provable loss to the claimant from the defendant's defaulted performance." Restatement (Third) of Restitution and Unjust Enrichment § 39 (2011), comment a. Similarly for Islet's unjust enrichment claim, that Restatement explains that "unjust enrichment is measured by the defendant's profits, where the object of restitution is to strip the defendant of a wrongful gain . . . [and] may potentially exceed any loss to the claimant." *Id*. § 51.

New York courts look to the Restatement for guidance. For example, in *Precision Testing Laboratories*, the court stated that, "[i]t is widely accepted that actions for restitution have for their primary purpose *taking from the defendant and restoring to the plaintiff something to which the plaintiff is entitled*."[8] 1988 WL 34825, at *2 (emphasis added) (citing Restatement of the Law of Restitution (1937) at 595). Moreover, that court explained, that while in instances of an innocent defendant, a plaintiff "is entitled to no more than the value of the benefit which he had conferred upon the other party," a fact scenario such as we have here—a set of opportunistic Defendants—is an instance in which case "the amount of recovery may exceed the value of the benefit conferred." *Id*. (quoting Restatement of the Law of Restitution (1937) at 449). Similarly, in *In re*

[8] The Parties agreed "that following [28 U.S.C. § 1404(a) transfer from New York to North Carolina] the transferee court will be obligated to apply the state law that would have applied if there had been no change of venue." ECF No. 55 (Apr. 9, 2019 Endorsed Letter).

Lyondell Chemical Company, the court noted that it "is also guided by the Restatement of Restitution in its calculation of damages here." 567 B.R. 55, 151 (Bankr. S.D.N.Y. 2017), aff'd, 585 B.R. 41 (S.D.N.Y. 2018); *see also id*. ("'When restitution is intended to strip the defendant of a wrongful gain, the standard of liability is not the value of the benefit conferred but the amount of the *profit* wrongfully obtained.'" (quoting Restatement (Third) of Restitution and Unjust Enrichment ¶49 (2011) (emphasis added))). Here, that profit is at least an apportioned measure of the disputed drugs.

Thus, Islet's claims extend to benefits provided to Defendants at the time of the joint venture or at any time thereafter. *See* SAC ¶¶ 36, 42, 43, 49, 71, 90, 91, 92, 116. In this Motion, the proposed amendment does nothing more than clarify that the scope of Islet's claims include *all* benefits resulting from Defendants' use of Remo—whether as a standalone monotherapy or in combination with other drugs. The claims in Islet's proposed amended complaint are viable, and the proposed amendment therefore should not be rejected as futile.[9]

IV. GOOD CAUSE EXISTS FOR THE PROPOSED AMENDMENT.

"Rule 16's 'good cause standard focuses on the timeliness of the amendment and the reasons for its tardy submission,' the primary consideration being the moving party's diligence." *Lorenzo v. Prime Commc'ns, L.P.*, No. 5:12-CV-69-H-KS, 2019 WL 8584866, at *1 (E.D.N.C. June 5, 2019) (quoting *Montgomery v. Anne Arundel Cnty., Md.*, 182 F. App'x 156, 162 (4th Cir. 2006)). "Thus, the moving party must show that it could not have reasonably met the deadline

[9] Defendants have suggested that these combination treatments are new drugs, or do not require Remo, and are thus beyond the scope of the Joint Venture. That assertion is false: Defendants have done nothing more than combine Remo with other ingredients. In any event, any such assertion would be but an assertion of fact, which is a merits-based contention that the Court cannot consider in evaluating the legal sufficiency of the proposed amendment. *See Johnson*, 785 F.2d at 510.

despite the party's diligence." *Id.* (quoting *Cook v. Howard*, 484 F. App'x 805, 815 (4th Cir. 2012)).

Good cause exists here for the proposed amendment. As discussed above, Islet believed the Complaint addressed all applications of Remo, and specifically described the applications that were known to Islet at the time. Indeed, Islet's Complaint explicitly alleged that Remo could be used for treatment of NASH—which, at the time the Complaint was drafted, Islet believed was Remo as a monotherapy. *See* SAC, ECF No. 53 ¶ 31. During the course of this litigation, however, Islet learned that this application of Remo was developed in a combination therapy that Defendants call AVO-3500—a combination of Remo and Miza. The addition of another molecule such as Miza, however, was never meant to be a material limitation to Islet's claims. The pleadings were always intended to capture all applications of Remo—including combination therapies.

The Court's rulings on Islet's first and second motions to compel seemed to confirm that scope. In granting the first motion to compel, the Court permitted discovery on "all applications" of Remo. *See* ECF No. 141 at 4; ECF No. 150. In denying the second motion, the Court ruled that drugs or technology "other than the Remo Technology"—meaning, the treatment "using the molecule Remogliflozin ('Remo') and its salt carrier ('Remo Etabonate')"—was "not relevant to [Islet's] damages claim." ECF No. 191 at 7. This suggested that any applications that used Remo would be considered within the scope of Islet's claims, and any applications that did not use Remo in some way would not. This, again, was consistent with Islet's intention and understanding all along: its claims address any and all applications of Remo. Until the Court's denial of Islet's motion for reconsideration on December 19, 2022, Islet understood that its pleadings addressed all uses of Remo, whether as a standalone monotherapy or in other prospective applications.

Islet acknowledges that Defendants disagreed with this position and that the Court has sided with Defendants. Now that the Court has made this decision, Islet moves to amend the Complaint to make the scope of its claims clear. Given that the Court's Order addressing the dispute was entered just this week, Islet could not have reasonably moved for leave to amend its pleadings earlier than it has. There is therefore good cause to permit the amendment, which will ensure full and fair adjudication of the entire dispute regarding Defendants' use of Remo.

CONCLUSION

For the foregoing reasons, Islet respectfully requests that the Court grant it leave to file the proposed Third Amended Complaint.

Dated: December 28, 2022

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on this 28th day of December, 2022, I electronically filed the foregoing with the Clerk of Court using the CM/ECF system.

By: /s/ *Robert C. Van Arnam*
Robert C. Van Arnam